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10/585,603

07/11/2006

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EXAMINER

MURRAY, JEFFREY H

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

03/16/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/585,603 | <b>Applicant(s)</b><br>FERLITA ET AL. |  |
|                              | <b>Examiner</b><br>JEFFREY H. MURRAY | <b>Art Unit</b><br>1624               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 37,38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/2/2006; 6/22/2007; &amp; 7/30/2007</u> .                   | 6) <input type="checkbox"/> Other: _____                          |



### DETAILED ACTION

1. This action is in response to an election from a restriction requirement filed on December 22, 2008. There are thirty-eight claims pending and thirty-six claims under consideration. Claims 37 and 38 have been withdrawn. This is the first action on the merits. This invention is directed generally to crystalline salts of a dipeptidyl peptidase-IV inhibitor. Election of Group I was made **without** traverse in the reply filed on December 22, 2008. Therefore this restriction is considered proper and thus made **FINAL**.

### *Priority*

2. It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/US2005/000951, filed January 12, 2005. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after

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November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its

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inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

### ***Specification***

3. The disclosure is objected to because of the following informalities: The specification is lacking the appropriate section: Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11. Appropriate correction is required.
4. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any of the errors of which applicant may become aware of in the specification.

### ***Claim Objections***

5. Claims 13-15, 18-21, 23-25, 28-30, and 33-35 are objected to because of the following informalities: Where possible, claims are to be complete in themselves. Incorporation by reference to tables or examples is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. See MPEP § 2173.05(s). Appropriate correction is necessary.

### ***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

6. Claims 16-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of an intended use, chemical activity, or functional description of some "additional" property for a compound (or moiety/functionality attached to a chemical core) or a composition containing same in a dependent claim, must result in a *tangible structural difference* between the product and of the independent claim and the product set forth in the dependent claim. In the absence of said structural difference between the product of the independent claim and that of the dependent claim, said dependent claim is seen to be a substantial duplicate, and said recitation is not afforded critical weight and fails to further limit the product in said dependent claim. In the instant set of claims, claims 16-35 fail to further limit the claims to compositions from which they depend.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

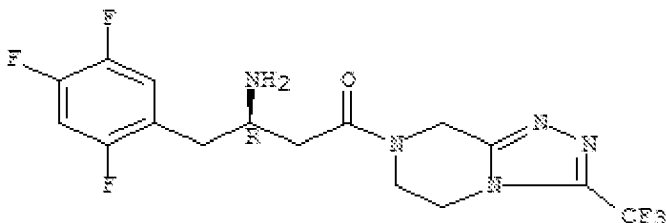
8. Claims 1, 2 and 36 are rejected under 35 U.S.C. 102(a) as being anticipated by Edmonson, et. al., WO2003004498.

Edmonson, et. al. demonstrates the synthesis of the following compound:

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RN 486459-71-6 CAPLUS  
 CN 1-Butanone, 3-amino-1-[5,6-dihydro-3-(trifluoromethyl)-1,2,4-triazolo[4,3-a]pyrazin-7(8H)-yl]-4-(2,4,5-trifluorophenyl)-, hydrochloride (1:1), (3R)-  
 (CA INDEX NAME)

Absolute stereochemistry.



● HCl

Which is the exact compound seen in the current application. The prior art process describes the final product as a solid, however does not use the term “crystalline”. Therefore the prior art is silent as to what “form” was isolated. Without further information provided, the examiner presumes the solid form which was isolated was crystalline.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:



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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 3-10 and 21-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edmonson, et. al., WO2003004498 in view of Stahl, et. al. Handbook of Pharmaceutical Salts, (2002), 1-374.

The current application is related to a triazolopyrazine compound, which is a dipeptidyl peptidase-IV inhibitor. In this application there is the presence of compound with the general formula 1, which contains a the compound, (2R)-4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine.

WO2003004498, herein referred to as '498, teaches the compound of (2R)-4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine. It also teaches the pharmaceutically acceptable salt, the hydrochloride salt. The '498 compound is identical to claims 3-10 of the current application except that the '498 document teaches only the hydrochloride salt, whereas the current application teaches additional pharmaceutically acceptable salts.

Stahl et. al. is a reference which is a review article on pharmaceutical salts and what constitutes an "acceptable pharmaceutical salt." The reference [points to several different salts which are considered "pharmaceutically acceptable." Among the salts listed are benzenesulfonic acid (page 273); p-toluenesulfonic acid (page 309-310); tartaric acid (page 308); and camphorsulfonic acid (page 309). The '498 document

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presents the exact compound of which applicants attempt to patent but for the fact it is a hydrochloric acid salt, not the additional aforementioned salts. The Stahl reference teaches all the salts listed within the current application as being pharmaceutically acceptable salts.

Claims 21, 26 and 31 refer to crystalline compounds which are characterized as "anhydrates". That is to say, the salt forms contain no water molecules. However, a chemist skilled in the art would not presume any water molecules are present unless the compound was listed as such (a monohydrate, a hemihydrate, etc.). In addition, several known procedures for synthesizing pharmaceutical salts require no water present, and therefore would lead to the anhydrate product regardless. For example, it is well known in the art to use HCl in a solvent other than water such as diethyl ether, methylene chloride, etc. when forming various salts. A compound reacted in a manner such as this, would yield the anhydrate salt form.

The '498 document teaches the hydrochloric acid salt form of the compound (2R)-4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine. Stahl, et. al., teaches that the salt forms mentioned in the current application are all pharmaceutically acceptable salt forms. A person of ordinary skill in the art, upon seeing this, would also have recognized the desirability of attempting to synthesize the various salt forms of (2R)-4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine. The Stahl et. al. reference teaches a finite number of pharmaceutically acceptable salts known to be useful in for formulation of salts of drugs.

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The Stahl et. al. reference also inherently discloses to one of ordinary skill in the art that combining a known drug with one of the anions disclosed in the reference in order to make a salt does not affect the therapeutic properties of the drug.

Thus, it would have been obvious to a person of ordinary skill in the art to make the various pharmaceutical salts of the Stahl et. al. reference of the compound (2R)-4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine in an attempt to provide an improved formulation of the compound, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp. In turn, because the drug product (2R)-4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine has the properties predicted by the prior art, it would have been obvious to make them with a pharmaceutically acceptable salt. No new matter permitted. Appropriate correction is required.

12. Claims 11-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edmonson, et. al., WO2003004498 in view of Cypes, et. al., U.S. Patent No. 7,326,708 and *In re Aller*, 105 USPQ 233 (C.C.P.A. 1955).

The current application is related to a triazolopyrazine compound, which is a dipeptidyl peptidase-IV inhibitor. In this application there is the presence of compound with the general formula 1, which contains a the compound, (2R)-4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine.

The '498 document teaches the compound of (2R)-4-oxo-4-[3-(trifluoromethyl)-

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5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine as a hydrochloride salt. The '498 compound is identical to claims 11-36 of the current application except that the '498 document teaches only the hydrochloride salt, whereas the current application teaches various salts either as a monohydrate, anhydrate or hemihydrate.

U.S. Patent No. 7,326,708, herein referred to as '708, also teaches the compound of (2R)-4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine. It teaches the compound as the phosphoric acid salt monohydrate. The '708 compound is identical to claims 11-36 of the current application except that the '708 document teaches only the phosphoric acid salt monohydrate, whereas the current application teaches various salts as a monohydrate, anhydrate or hemihydrate.

The '498 document teaches the hydrochloric acid salt form of the compound (2R)-4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine. The '708 document teaches that the same compound as a phosphoric acid salt monohydrate. One skilled in the art would instantly recognize that varying the salt forms of final compounds is an every day common practice in the lab in order to obtain various results such as better solubility in water and more stability. The '498 document teaches the limitations of claims 11-35 but for the specific salt forms and their hydrate ratios. Altering a compound by changing its salt form is extremely well known in the chemical arts. It can be seen in a variety of reactions in the chemical realm. In addition, determining the formation, or lack thereof,

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of a hydrate is inherently dependent on what salt form is made. For example, applicants synthesized several different salt forms in the current application, but no specific process was used to make a hydrate, anhydrate or hemihydrate. The hydrate forms or lack thereof were formed during the routine experimentation of making the salt forms.

One skilled in the chemical arts would attempt several different salt forms of pharmaceutically acceptable salts in order to determine the best conditions for their particular final compound. Indeed, Stahl et. al. teaches us, "An estimated half of all drug molecules used in medical therapy are administered as salts, and salification of drug substance has become an essential step in drug development." (page 2 ). The claims here do nothing more than take ordinary routine chemistry and try to patent it. Changing the salt form of final product and determining if it is a hydrate are not patentable modifications. "The claims differ by varying the process conditions. However, selection of the appropriate process conditions would have been prima facie obvious because where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 105 USPQ 233. The claims are rejected as being unpatentable over the '498 document in view of the '135 document and *In re Aller*, 105 USPQ 233 (C.C.P.A. 1955). A person of ordinary skill in the art, upon seeing this, would also have recognized the desirability of attempting to synthesize the (2R)-4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazole-[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine as the various salt forms listed in the claims.

Thus, it would have been obvious to a person of ordinary skill in the art to make the compound (2R)-4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine as various salt forms hydrochloride salt monohydrate in an attempt to provide an improved formulation of the compound, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp. No new matter permitted. Appropriate correction is required.

***Double Patenting***

13. Applicant is advised that should claim 11 be found allowable, claims 12-15 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

14. Applicant is advised that should claim 16 be found allowable, claims 17-20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

15. Applicant is advised that should claim 21 be found allowable, claims 22-25 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both

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cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).

16. Applicant is advised that should claim 26 be found allowable, claims 27-30 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).

17. Applicant is advised that should claim 31 be found allowable, claims 32-35 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

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by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent No. 6,699,871. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 17 of U.S. Patent No. 6,699,871 embraces the instant claims 1-35.

The instant claim differs from the copending claim by a more limited genus than the claim of the copending application. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of



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the genus of the copending application, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus of the copending application since such compounds would have been suggested by the claims of the copending application. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

20. Claims 1-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 17 of U.S. Patent No. 7,326,708 in view of Stahl et. al.

The reasoning for this double patenting rejection is explained in the 103(a) rejection above citing the same reference. No new matter permitted. Appropriate correction is required.

### **Conclusion**

21. Claims 1-36 are rejected.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon.-Thurs. 7:30-6pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisors, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H Murray/  
Examiner, Art Unit 1624

**/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624**